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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,333	07/31/2000	Anand C. Burman	U 012799-1	5586

140 7590 12 26 2001

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/630,333	Applicant(s) BURMAN ET AL.	
	Examiner Abdel A. Mohamed	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF IDS, SEQUENCE LISTING, PRELIMINARY AMENDMENT, RESPONSE TO RESTRICTION REQUIREMENT, STATUS OF THE CLAIMS AND APPLICATION

1. This application is filed as a Continuation-in-part (CIP) of U.S. Patent Application Serial Nos. 09/248,382, filed 2/10/99 and 09/248,381, filed 2/11/99, which claims benefit of Provisional Application Serial No. 60/080,433, filed 4/2/98 and a CIP of U.S. Patent Application Serial No. 08/727,679, filed 10/8/96, now U.S. Patent No. 6,156,725. Acknowledgment is made of Applicant's claim for priority based on Indian Application Numbers 147/DEL/2000, 343/DEL/98, 342/DEL/98 and 1822/DEL/96, filed 2/24/00, 2/11/98, 2/11/98 and 8/16/96, respectively. Only the certified copy of Indian Application Number 147/DEL/2000 having a filing date of 2/24/2000 is acknowledged, although, the certified copies of above three Indian applications (i.e., 343/DEL/98, 342/DEL/98 and 1822/DEL/96, filed 2/11/98, 2/11/98 and 8/16/96, respectively) have not been submitted, however, receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The Information Disclosure Statement (IDS) and Form PTO-1449 filed 7/31/00 and 3/7/01, respectively and also, the sequence listing, the preliminary amendment and the response to the restriction requirement filed 10/24/00, 2/26/01 and 10/1/01, respectively are acknowledged, entered and considered. Claims 1-20 are present for examination.

ELECTION WITH TRAVERSE

2. Applicant's election with traverse of Group I (claims 1-12) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that there would be no significant burden on the Examiner if Group I and Group II (i.e., claims 1-14) are examined together in the present application because if the peptides are found to be novel and non-obvious, a composition containing such novel and non-obvious peptides would also be novel and non-obvious. In addition, Applicant believes that searches of the claims of Groups I and II would essentially co-extensive, and the Examiner is requested to re-combine Groups I and II and to examine each of the claims 1-12 and 13-14 on the merits is persuasive. Therefore, as per Applicant's request, the Examiner has rejoined the peptide and a composition of Group II (elected) to the method of treatment of cancer of Group II since the treatment claimed uses the peptide disclosed in Group I. With respect to election of species, Applicant has elected the species of SEQ ID NO:11 described in claim 10. Thus, claims 15-20 (Group III) are withdrawn as non-elected invention in view of Applicant's grouping of the claims and in view for the reasons discussed above; hence, the Office action is directed to the merits of claims 1-14 as per elected invention.

The requirement is still deemed proper and is therefore made FINAL.

OBJECTIONS TO TRADEMARKS AND THEIR USE

3. The use of trademarks "LichroCART® C,8" and "C 18 Lichrospheng® WP-300" have been noted in this application. The trademarks have not been capitalized, they should be capitalized whenever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks.

Further, the specification which specifies the generic terminology should include published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirement are made because the nature and composition of articles denoted by trademark can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. 112 [1st] PARAGRAPH.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the synthesis/preparation of peptide composition comprising a peptide of the general formula I and peptides of SEQ ID NOS:3-12 and using the above peptides at different

concentrations individually *in vitro* to determine the cytotoxicity effect or activity of the peptides in various human cell lines, does not reasonably provide enablement for a therapeutically effective pharmaceutical composition containing individual peptides for treatment of cancer in mammals including humans and to a method of administering a therapeutic compound thereof as recited in claims 13-14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims; e.g., claim 13 is directed to "*in vivo*" "treatment" of any kind of cancer by administering "an effective amount" of the peptide of claim 1; and claim 14 to a method of administering a chemotherapeutic compound of peptide of claim 11, and as to the rest of the claims, they are directed to pharmaceutical compositions comprising the peptide composition claimed in claim 1 and the various sequences of claims 2-11.

The instant specification on page 8, lines 1-27 states that the present invention envisages methods and treatment of cancer using the polypeptides of the present invention, pharmaceutical compositions comprising such polypeptides and process for their preparation. However, except for synthesis of the polypeptides claimed which is disclosed in Examples 1-11 and Examples 12-14 which show the biological activities of the peptides *in vitro* by using cytotoxicity assays such as MTT in human tumor cell lines. The above disclosure and the mere recitation of protocols on page 8 would not entitle Applicant to a method of treatment of cancer in mammal in general by administering an effective amount of the polypeptides claimed because the scope of the instantly claimed invention are very broad and speculative in that there is no working example or data or

evidence which shows that the claimed peptides individually are useful as a pharmaceutical composition by administering as an active ingredient a therapeutically effective amount of the peptide to treat cancer in mammals including humans in the manner claimed in the instant invention. There is no evidence in the instant specification to use or administer the pharmaceutical formulation in therapeutically effective composition as claimed. There is no dosage amount for pharmaceutical composition disclosed, except for the various *in vitro* assays which show the cytotoxicity effect or activity in human tumor cell lines with different concentrations of peptides and analogs as disclosed in Examples 12-14 and the various Tables showing cytotoxicity percentages in the instant specification. Thus, there are no sufficient data or evidence to substantiate such protocols of using a therapeutically effective pharmaceutical composition for treating cancer in general in the manner claimed. Hence, the only support for the claimed therapeutically effective pharmaceutical composition and method of treatment of cancer in mammals by administering a therapeutically effective dose of the pharmaceutical composition thereof in the specification is Applicant's supposition of the invention as recited in the protocols. Furthermore, Applicant's claims are directed to a very large number of compounds by using specific therapeutically effective amount of pharmaceutical composition, and there are no objective factual evidence in the specification showing that treatment has occurred using the specific therapeutically effective amount of pharmaceutical composition claimed. Thus, it is the Examiner's position that one can not administer specific effective amount of a pharmaceutical

composition in all situations without appropriate testing which would require the exercise of undue experimentation, as for example, treating cancer in general in mammals.

Therefore, in view of the above, it would include those that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since a vast range of pharmaceutical composition in all kinds of possible compounds are contemplated and are encompassed as well as wide range of situations. The results desired appear to be highly dependent on all variables, the relationship of which are not present in the specification. Hence, one of ordinary skill in the art would not be able to identify all the pharmaceutical preparations with the various peptides either alone or in combination having all kinds of concentrations intended to be effective for the claimed purpose as encompassed in the claims would be effective and under what conditions.

Further, the first paragraph of 35 U.S.C. 112 requires, inter alia, that a patent specification provide sufficient guidance to enable a person skilled in the art to make and use the claimed invention without undue experimentation. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). While patent Applicants are not directed to disclose every species that falls within a generic claim, id. At 496, 20 USPQ2d at 1445, it is well settled that "the scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification". In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Where practice of the full scope of the claims would require experimentation; factors to be considered in

determining whether a disclosure would require undue experimentation ..... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Therefore, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims fro the reasons given above. Thus, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data. and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is suggested.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in failing to recite as to the function or activity or use of the peptide pf the formula referred in claim 1 (i.e., it is not clear what the peptide recited in claim 1 is supposed to do).

Claims 13 and 14 are indefinite in the recitation "....administration of an effective amount...." and ".....administering a chemotherapeutic.....", respectively because it is not clear what is meant by the terms "effective amount" and "chemotherapeutic" since no amount of peptide or chemotherapeutic compound is claimed or disclosed, and as such, the metes and bounds of the claims cannot be determined.

CONCLUSION AND FUTURE CORRESPONDENCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low

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AAM Mohamed/AAM

December 20, 2001